REMARKS

I. Preliminary Remarks

The Applicants thank the Examiner and his Supervisor for the courtesy and interest shown during the interview of February 22, 2005 during which it was agreed that the applicants would provide further clarification on differences between the cited art and instant invention.

A. The Rejections Under 35 U.S.C. §§ 102(b) and 102(e).

The rejections under 35 U.S.C. §§ 102(b) and 102(e) in view of Eisenbach *et al.* (EP 0569678 A2) and Eisenbach *et al.* (U.S. Patent No. 5,750,102), respectively, are maintained for reasons of record. These remarks will address both of cited the references simultaneously as the teachings are the same.

The Examiner has reiterated under both §§ 102(b) and 102(e) that the term antigen presenting cells as used in the present claims is not limited to professional or constitutive APCs and that the tumor cells taught by Eisenbach are considered antigen presenting cells and would inherently comprise total genomic DNA from tumor cells. The Examiner states further that

> "[B]ecause the transfection of genomic DNA into the antigen presenting cells is a process of making the product (*i.e.*, product-by-process, which is not given any patentable weight unless the process by which the product is made creates a structurally different product) and because the method of Eisenbach *et al.* appears to the use the same product, from the absence of evidence to the contrary, the methods will produce the same effects and is thus anticipated."

(Office Action at page 3)

The Applicants respectfully traverse the rejection in view of the fact that the product made according to the presently claimed method is in fact structurally different from that described in the Eisenbach *et al.* references and therefore it cannot be anticipated by those references.

The Eisenbach references describe the transfection cloned MHC encoding sequences into tumor cells taken from a patient to be treated. These cells are different in a number of ways from those prepared by the method of the present invention. First, the presently claimed method does not involve the transfection of tumor cells as described in the Eisenbach references, but rather involves transfecting the genomic DNA derived from a patient's tumor cells into an antigen presenting cell (not the patient's tumor cells) and ultimately producing semi-allogeneic cells that express at least class I MHC or class II MHC determinant that is syngeneic to the animal from whom the tumor DNA was derived and at least one class one or class two MHC determinant that is allogeneic to the animal from whom the tumor cell DNA is derived. The cells used in the methods of the present invention contain genomic DNA obtained from the patient's tumors as well as their own endogenous genomic DNA. Thus, the cells described in the present claim are different from the tumor cells transfected with cloned MHC determinants as described by Eisenbach. Because the presently claimed methods and the products encompassed by those methods differ from those described in the Eisenbach references, the Applicants respectfully submit that the rejections under 35 U.S.C. §§ 102(b) and 102(e) should be withdrawn.

B. The Rejection of Claims 47-53 Under 35 U.S.C. § 112, first paragraph Should be Withdrawn

The Examiner has maintained the rejection of Claims 47-53 under 35 U.S.C. § 112, first paragraph, stating that the specification provides insufficient guidance and objective evidence to predictably enable one of skill in the art to use the invention as claimed. The Examiner stated that the specification teaches at page 36, second full paragraph, that "preventing a tumor means the occurrence of the tumor is prevented." However, the Applicants wish to point out that the claims do not currently recite a method of preventing occurrence of tumor but rather a method of *inhibiting recurrence* of a tumor which necessarily means that it is the same tumor type for which the patient was previously treated using cells of the present invention. Recurrences typically occur as a result of residual micrometastasis from the original tumor that may have been too small to detect. Left untreated, the tumor may recur as a result of the growth of such metastasis. As discussed in response to the previous office action, the specification provides examples of such inhibition, for example, in Example 15, on pages 72-74, which describes animals who had previously been injected with both breast tumor cells and a breast cancer vaccine that were subsequently challenged with a second injection of cancer cells. Naive mice who had not been exposed either to the vaccine or the breast tumor cells were also injected with breast cancer cells with no vaccine, and both groups were monitored for survival. The mean survival time of those mice who were previously vaccinated (treated) was significantly higher than those who had not previously received the vaccine suggesting that the previously treated mice had developed at least partial immunity against subsequent tumor challenge as measured by an increased mean survival time when compared to naive mice

receiving the breast cancer cells alone. Because the instant specification provides working examples supporting the conclusion that the methods of the instant invention are able to increase the mean survival time, *i.e.,* inhibit the recurrence of the tumor for which the animals originally treated, the applicants are respectfully submit that the application fulfills the requirements of 35 U.S.C. § 112, first paragraph, and therefore, the rejection should be withdrawn.

C. The Rejections of Claims 26, 1-46, and 54 Were Rejected Under 35 U.S.C. § 112, First Paragraph (Written Description) Should Be Withdrawn.

In rejecting the claims under 35 U.S.C. § 112, first paragraph, the Examiner alleges that the insertion of the word "total" into claim 26 constitutes new matter as the term "total" does not find support in the specification as filed. This rejection is now moot in view of the foregoing amendment that was made to expedite prosecution and is not intended to indicate acquiescence to the rejection. The claim as currently amended simply recites "the genomic DNA" isolated from the tumor cells of the animal to be treated. Nevertheless, the applicants respectfully disagree with the Examiner's new matter assertion in that a person of ordinary skill in the art reading the specification would know that the application was, in fact, describing the isolation and use of total genomic DNA. *Ipsis verbis* support for such a term is not required in view of the description set out in the specification.

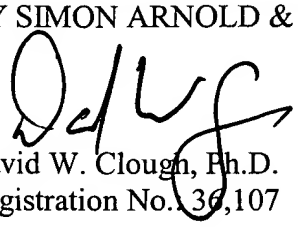
Conclusion

Applicant respectfully submits that the amended claims are in condition for allowance and early notification thereof is requested. If in the interest of expediting

prosecution, the Examiner has questions or comments he is invited to telephone the undersigned at the indicated telephone number.

Respectfully submitted,

HOWREY SIMON ARNOLD & WHITE, LLP

By: 

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